

Applicant: Gyure et al.  
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### REMARKS

Reconsideration of the application as amended is respectfully requested.

Claims 30-38 are in the application. Claim 30 has been amended. Claim 35 has also been amended to correct a typographical error.

In the Office Action, the Examiner rejected claims 30-38 under 35 U.S.C. §103(a) as being allegedly unpatentable over Pirtle, Jr. in view of Funderburk (U.S. Patent No. 5,456,940), Richard, et al. (U.S. Patent No. 4,252,118), Akhavi (U.S. Patent No. 4,266,559), Tischlinger (U.S. Patent No. 3,889,351) or Dragosits, et al. (U.S. Patent No. 5,147,328). The Examiner asserted that the coating 20 of Pirtle, Jr. corresponds to the claimed lubricant and that the plunger tip 18 of Pirtle, Jr. corresponds to the claimed stopper.

Pirtle, Jr. is directed to a syringe for the injection of radioactive medicinal and diagnostic compositions into the body. The syringe includes a cylindrical body 10 formed of lead glass, with a hypodermic needle 13 being attached thereto. A stainless steel plunger 15 is slidably disposed within the cylindrical body 10. As indicated at column 1, lines 63-65, the stainless steel plunger is "adapted for slidable engagement with the inner wall of said cylindrical body [by being] coated with a soft resilient material selected from the group consisting of resilient polymeric materials, rubber and combinations of these." See, also column 3, lines 13-16. Lubrication between the inner wall of the cylindrical body 10 and the plunger 15 is achieved by providing the resilient material 20 on the plunger 15, not on the inner surface of the body. Pirtle, Jr. neither teaches nor suggests depositing lubricant on the inner wall of the cylindrical body. In

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fact, Pirtle, Jr. clearly teaches away from such a method of lubricating a syringe body by disclosing that the lubricant, i.e., the soft resilient material, is deposited only on the steel plunger.

Claim 30 is directed to a method of depositing a lubricant directly on an inner surface of a medical container. Claim 35 is directed to a medical container which has "lubricant deposited in accordance with the method of claim 30." In contrast, the coating 20 in Pirtle, Jr. is provided on the plunger rod - not on the inner surface of the medical container. As noted above, applicants respectfully submit that Pirtle, Jr. teaches away from their invention by teaching providing the lubricant only on the plunger rod. Pirtle, Jr. provides no other teaching or suggestion about alternative ways to provide lubricant in a medical container. Importantly, Pirtle, Jr. discloses only to provide a lubricant on the plunger rod. There is no suggestion or disclosure in Pirtle, Jr. to provide the coating 20 directly to the cylindrical body 10 below the plunger tip 18 or elsewhere on the cylindrical body 10.

It appears that the Examiner relied on the combination of Pirtle, Jr. and Funderburk against claims 32-34. Funderburk, as noted by the Examiner, is directed to a system for lubricating a syringe barrel. Further, Funderburk relates to "substantially uniform surface coating of interior surfaces of the syringe barrel." (Abstract). There is no disclosure or suggestion in Funderburk to lubricate only a portion of the inner surface of the barrel. Each of claims 32-34 relates, *inter alia*, to providing lubricant on the outer surface of a stopper. There is no disclosure of such in Funderburk. In formulating the rejection, the Examiner stated that:

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Importantly, Pirtle, Jr., demonstrates that it is conventional to lubricate only a portion of the syringe barrel. Moreover, in Figure 2, as the plunger moves up and down, it is apparently clear that sealing rings (19) would be lubricated to reduce friction and enhance the movement of the plunger. Based on the above observations, a person of ordinary skill in the art would have considered the step of coating the sealing rings of the stopper an obvious design alternative.

Contrary to the Examiner's assertion, Pirtle, Jr. does not in fact demonstrate that it is conventional to lubricate alone only a portion of the syringe barrel. As noted above, Pirtle, Jr. teaches only providing lubricant on the plunger, and says nothing about providing lubricant directly on an inner surface of a medical container, as recited by applicants' claim 30. In sum, neither Funderburk nor Pirtle, Jr. disclose providing a lubricant on a stopper, as recited by claims 32-34, and it is respectfully submitted that claims 32-34 are patentable.

Richard et al. is directed to a non-reusable, drug pre-filled syringe assembly. It appears that the Examiner relied on the combination of Pirtle, Jr. and Richard et al. against claim 36. Claim 36 depends from claim 30. Richard et al. discloses only the use of conventional lubricants (column 5, lines 21-25). Accordingly, the hypothetical combination of Pirtle, Jr. and Richard et al. fails to disclose a depositing a lubricant directly on an inner surface of a medical container, yet only over a limited area of the inner surface, the limited area having an axial length greater than an axial length of the stopper, as recited by applicants' claim 30. Moreover, the proposed hypothetical combination of Pirtle, Jr. and Richard et al. teaches providing a lubricant on the plunger - contrary to applicants' claimed invention. It is respectfully submitted that claim 36, as

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depending from claim 30, is patentable over Pirtle, Jr. and Richard et al., each taken alone or in combination.

Akhavi is directed to a blood sampler. It appears that the Examiner relied on the combination of Pirtle, Jr. and Akhavi against claim 37. Claim 37 depends from claim 30. It does not appear that Akhavi discloses any specifics as to the application of a lubricant on a syringe barrel. Accordingly, Akhavi fails to overcome the deficiencies noted above with respect to Pirtle, Jr. It is respectfully submitted that claim 37, as depending from claim 30, is patentable over Pirtle, Jr. and Akhavi, each taken alone or in combination.

Tischlinger is directed to a method of assembling a glass tube and plastic parts to form a syringe body assembly. A general discussion of the use of silicone coating is found in Tischlinger at column 10, lines 28-40. There is, however, no specific discussion of the use of lubricant as set forth in claim 30. Accordingly, the hypothetical combination of Pirtle, Jr. and Tischlinger fails to disclose the use of lubricant to reduce friction between the inner surface of a medical container and a stopper, with that same lubricant being arranged only over a limited portion of the medical container as set forth in claim 30. It is respectfully submitted that claim 38, as depending from claim 30, is patentable over Pirtle, Jr. and Tischlinger, each taken alone or in combination.

The Examiner stated "Dragosits, et al., demonstrates the conventionality of reducing friction in a syringe by applying a lubricant to the piston and/or the inner portion [referring to the inner wall of the syringe]." Since Dragosits, et al. only discloses conventional lubricating, as set

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forth by the Examiner, Dragosits, et al. does not overcome the deficiencies of Pirtle, Jr. noted above. Specifically, the hypothetical combination of Pirtle, Jr. and Dragosits, et al. would result in the Pirtle, Jr. having an inner surface fully coated with lubricant, as in a conventional manner, and a plunger with a lubricant applied thereto, not the arrangement of claim 30. It is respectfully submitted that claims 30, 31 and 35 are patentable over Pirtle, Jr. and Dragosits, et al., each taken alone or in combination.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



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